AMENDMENTS TO THE CLAIMS

The listing of claims below will replace all prior versions and listing of claims in the application.

– 137. (Canceled)

138. (Previously Presented) A unit dose of a controlled release pharmaceutical formulation, wherein said formulation comprises melt extruded multiparticulates comprising a rubbery matrix including a neutral poly(ethyl acrylate, methyl methacrylate) copolymer and an active agent.

139. (Previously presented) The unit dose of claim 138, wherein said active agent is selected from the group consisting of an opioid, a stimulant, a barbiturate, an anti-depressant a dissociative anaesthetic, and any two or more of the foregoing.

140. (Previously presented) The unit dose of claim 139, wherein said active agent is oxycodone, or a pharmaceutically acceptable salt thereof.

141. (Canceled).

142. (Previously presented) The unit dose of claim 138, wherein said matrix includes at least one other polymer to modify release.

143. (Previously presented) The unit dose of claim 142, wherein said other polymer is selected from the group consisting of an alkyl cellulose and a water insoluble ammonium methacrylate copolymer.

144. (Previously presented) The unit dose of claim 143, wherein said other polymer is ethyl cellulose.

145. (Previously presented) The unit dose of claim 144, wherein said amount of ethyl cellulose is 10 to 50% by weight of the formulation.

146. (Previously presented) The unit dose of claim 138, which comprises the following amounts of ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

147. (Previously presented) The unit dose of claim 138, which comprises up to 60% w/w of said active agent, 15 to 50% w/w of neutral poly(ethyl acrylate, methyl methacrylate) copolymer; 5 to 60% w/w of ethyl cellulose; and 7.5 to 20% of plasticiser.

148. (Previously presented) The unit dose of claim 147, which further contains 5 to 60% of an insoluble ammonium methacrylate copolymer.

149. (Previously presented) The unit dose of claim 148, which contains 35 to 50% of an insoluble ammonium methacrylate copolymer which is of low permeability and/or 5 to 30% of an ammonium methacrylate copolymer which is highly permeable.

150. (Previously presented) The unit dose of claim 138, which contains a bulking agent.

151. (Previously presented) The unit dose of claim 138, which contains an opioid and an opioid antagonist.

152. (Previously presented) The unit dose of claim 151, which comprises 120 to 300 mg of oxycodone multiparticulates and 125 to 175 mg of oxycodone antagonist multiparticulates.

153. (Previously presented) The unit dose of claim 138, which contains oxycodone and naltrexone.

154. (Previously presented) The unit dose of claim 138, which contains oxycodone in an amount selected from the group consisting of 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 120 mg and 160 mg of oxycodone.

155. (Previously presented) The unit dose of claim 138, suited for once a day dosing.

156. (Previously presented) The unit dose of claim 155, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH between 1.6 and 7.2 at 37°C of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80% at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hours, and greater than about 50% at 24 hours.

157. (Previously presented) The unit dose of claim 156, wherein the peak plasma level of oxycodone obtained in vivo occurs at 2 hours to 17 hours after administration of the unit dose.

158. (Previously presented) The unit dose of claim 155, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method <<7 11>> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 10 to 30% at 1 hour; from 20 to 35% at 2 hours; from 35 to 75%, at 8 hours; and greater than 50% at 16 hours.

159. (Previously presented) The unit dose of claim 138, suited for twice a day dosing.

160. (Previously presented) The unit dose of claim 159, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Paddle Method of the U.S. Pharmacopoeia XXII (1990) at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C of between 12.5 and 42.5% (by wt) oxycodone released after 1 hour, between 25 and 56% (by wt) oxycodone released after 2 hours, between 45 and 75% (by wt) oxycodone released after 4 hours and between 55 and 85% (by wt) oxycodone released after 6 hours.

161. (Previously presented) The unit dose of claim 159, wherein the active ingredient is oxycodone, and which has an oxycodone

dissolution rate in vitro, when measured using the USP Basket Method << 7 11 >> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 0 to 40% at 1 hour; from 20 to 70%, at 2 hours; from 40 to 80%, at 3 hours; from 60 to 95%, at 4 hours; and greater than 70% at 5 hours.

162. (Previously presented) The unit dose of claim 161, wherein the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the unit dose.

163. (Canceled)

164. (Previously presented) The unit dose of claim 138, which shows at least one of the following characteristics (a) to (e) when tested by a test method comprising admixing a dosage amount of multiparticulates with 10 ml of the liquid in a glass flask and shaking at 500 to 600 oscillations per minute for 15 minutes using a Stuart Scientific Shaker Model SF1:

a. 15 minutes shaking in water at room temperature: less than 7.5% release of active agent;

b. 5 minutes standing in water at 50°C followed by 15 minutes shaking at the same temperature: less than 15% release of active agent;

c. 5 minutes standing at 75°C followed by 15 minutes shaking at the same temperature: less than 20% release of active agent;

d. 5 minutes standing at 100°C followed by 15 minutes shaking at the same temperature: less than 25% release of active agent;

e. 15 minutes shaking in 40% ethanol at room temperature: preferably less than 25% release of active agent.

165. (Previously presented) A plurality of a controlled release granulates comprising a rubbery matrix including a neutral poly(ethyl acrylate, methyl methacrylate) copolymer and an active agent.

166. (Previously presented) The plurality of controlled release granulates of claim 165, wherein said active agent is selected from the group consisting of an opioid, a stimulant, a barbiturate, an anti-depressant, a dissociative anaesthetic, and any two or more of the foregoing.

167. (Previously presented) The plurality of controlled release granulates of claim 166, wherein said active agent is oxycodone, or a pharmaceutically acceptable salt thereof.

168. (Previously presented) The plurality of controlled release granulates of claim 165, wherein said matrix includes at least one other polymer to modify release.

169. (Previously presented) The plurality of controlled release granulates of claim 168, wherein said other polymer is selected from the group consisting of an alkyl cellulose and a water insoluble ammonium methacrylate copolymer.

170. (Previously presented) The plurality of controlled release granulates of claim 169, wherein said other polymer is ethyl cellulose.

171. (Previously presented) The plurality of controlled release granulates of claim 170, wherein said amount of ethyl cellulose is 10 to 50% by weight of the plurality of controlled release granulates.

172. (Previously presented) The plurality of controlled release granulates of claim 165, which comprises the following amounts of ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

173. (Previously presented) The plurality of controlled release granulates of claim 165, which comprises up to 60% w/w of said active agent, 15 to 50% w/w of neutral poly(ethyl acrylate, methyl methacrylate) copolymer; 5 to 60% w/w of ethyl cellulose; and 7.5 to 20% of plasticiser.

174. (Previously presented) The plurality of controlled release granulates of claim 173, which further contains 5 to 60% of an insoluble ammonium methacrylate copolymer.

175. (Previously presented) The plurality of controlled release granulates of claim 174, which contains 35 to 50% of an insoluble ammonium methacrylate copolymer which is of low permeability and/or 5 to 30% of an ammonium methacrylate copolymer which is highly permeable.

176. (Previously presented) The plurality of controlled release granulates of claim 165, which contains a bulking agent.

177. (Previously presented) The plurality of controlled release granulates of claim 165, which contains an opioid and an opioid antagonist.

178. (Previously presented) The plurality of controlled release granulates of claim 177, which comprises 120 to 300 mg of oxycodone granulates and 125 to 175 mg of oxycodone antagonist granulates.

179. (Previously presented) The plurality of controlled release granulates of claim 165, which contains oxycodone and naltrexone.

180. (Previously presented) The plurality of controlled release granulates of claim 165, which contains oxycodone in an amount selected from the group consisting of 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 120 mg and 160 mg of oxycodone.

181. (Previously presented) The plurality of controlled release granulates of claim 165, suited for once a day dosing.

182. (Previously presented) The plurality of controlled release granulates of claim 181, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH between 1.6 and 7.2 at 37°C of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80%

at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hours, and greater than about 50% at 24 hours.

183. (Previously presented) The plurality of controlled release granulates of claim 182, wherein the peak plasma level of oxycodone obtained in vivo occurs at 2 hours to 17 hours after administration of the dosage form.

184. (Previously presented) The plurality of controlled release granulates of claim 181, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method <<7 11>> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 10 to 30% at 1 hour; from 20 to 35% at 2 hours; from 35 to 75%, at 8 hours; and greater than 50% at 16 hours.

185. (Previously presented) The plurality of controlled release granulates of claim 165, suited for twice a day dosing.

186. (Previously presented) The plurality of controlled release granulates of claim 185, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Paddle Method of the U.S. Pharmacopoeia XXII (1990) at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C of between 12.5 and 42.5% (by wt) oxycodone released after 1 hour, between 25 and 56% (by wt) oxycodone released after 2 hours,

between 45 and 75% (by wt) oxycodone released after 4 hours and between 55 and 85% (by wt) oxycodone released after 6 hours.

187. (Previously presented) The plurality of controlled release granulates of claim 185, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method << 7 11 >> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 0 to 40% at 1 hour; from 20 to 70%, at 2 hours; from 40 to 80%, at 3 hours; from 60 to 95%, at 4 hours; and greater than 70% at 5 hours.

188. (Previously presented) The plurality of controlled release granulates of claim 187, wherein the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the dosage form.

189. (Previously presented) The plurality of controlled release granulates of claim 165, which shows at least one of the following characteristics (a) to (e) when tested by a test method comprising admixing a dosage amount of controlled release granulates with 10 ml of the liquid in a glass flask and shaking at 500 to 600 oscillations per minute for 15 minutes using a Stuart Scientific Shaker Model SF1:

a. 15 minutes shaking in water at room temperature: less than 7.5% release of active agent;

b. 5 minutes standing in water at 50°C followed by 15 minutes shaking at the same temperature: less than 15% release of active agent;

c. 5 minutes standing at 75°C followed by 15 minutes shaking at the same temperature: less than 20% release of active agent;

d. 5 minutes standing at 100°C followed by 15 minutes shaking at the same temperature: less than 25% release of active agent;

e. 15 minutes shaking in 40% ethanol at room temperature: preferably less than 25% release of active agent.

190. (Withdrawn) A method of imparting tamper resistance in a pharmaceutical formulation, which comprises admixing an active agent and a neutral poly(ethyl acrylate, methyl methacrylate) copolymer to form a pharmaceutical formulation incorporating the active agent in a matrix with the neutral poly(ethyl acrylate, methyl methacrylate) copolymer.

191. (Withdrawn) The method of claim 190 wherein the step of admixing comprises melt extrusion of the active ingredient and the neutral poly(ethyl acrylate, methyl methacrylate) copolymer to form extruded strands.

192. (Withdrawn) The method of claim 191 wherein the extruded strands are cut to form melt extruded multiparticulates.

193. (Withdrawn) The method of claim 192 wherein the pharmaceutical formulation is a controlled release formulation and the matrix comprises at least one other polymer to modify the release rate of the active agent.

194. (Withdrawn) The method of claim 193 wherein the matrix comprises the following ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

195. (Withdrawn) The method of claim 194 wherein the active agent is an opioid or a pharmaceutically acceptable salt thereof.

196. (Withdrawn) The method of claim 195 wherein the active agent is oxycodone or a pharmaceutically acceptable salt thereof.

197. (Withdrawn) The method of claim 195 wherein the matrix further comprises an opioid antagonist or a pharmaceutically acceptable salt thereof.

198. (Withdrawn) The method of claim 196 wherein the matrix further comprises naltrexone or a pharmaceutically acceptable salt thereof.

199. (Withdrawn) The method of claim 190 wherein the step of admixing comprises granulation of the active agent and the neutral poly(ethyl acrylate, methyl methacrylate) copolymer to form granulates.

200. (Withdrawn) The method of claim 199 wherein the pharmaceutical formulation is a controlled release formulation and the

matrix comprises the following ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

201. (Withdrawn) The method of claim 200 wherein the active agent is an opioid or a pharmaceutically acceptable salt thereof.

202. (Withdrawn) The method of claim 201 wherein the active agent is oxycodone or a pharmaceutically acceptable salt thereof.

203. (Withdrawn) The method of claim 201 wherein the matrix further comprises an opioid antagonist or a pharmaceutically acceptable salt thereof.

204. (Withdrawn) The method of claim 202 wherein the matrix further comprises naltrexone or a pharmaceutically acceptable salt thereof.

205. (Withdrawn) A process for preparing a tamper resistant controlled release pharmaceutical formulation which comprises admixing a neutral poly(ethyl acrylate, methyl methacrylate) copolymer and an active agent to form a matrix.

206. (Withdrawn) The process of claim 205 wherein the step of admixing comprises melt extrusion to form extruded strands. ,

207. (Withdrawn) The process of claim 206 wherein the melt extrusion is performed in a twin screw extruder.

208. (Withdrawn) The process of claim 206 wherein the extruded strands are conveyed to a pelletizer which cuts the extruded strands into melt extruded multiparticulates.

209. (Withdrawn) The process of claim 205 wherein the step of admixing comprises granulation.

210. (Withdrawn) The process of claim 209 wherein the neutral poly(ethyl acrylate, methyl methacrylate) copolymer is provided in the form of an aqueous dispersion comprising 40% by wt. of the copolymer.

211. (Previously added) A plurality of controlled release melt extruded multiparticulates comprising a rubbery matrix including a neutral poly(ethyl acrylate, methyl methacrylate) copolymer and an active agent.

212. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, wherein said active agent is selected from the group consisting of an opioid, a stimulant, a barbiturate, an anti-depressant, a dissociative anaesthetic, and any two or more of the foregoing.

213. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 212, wherein said active agent is oxycodone, or a pharmaceutically acceptable salt thereof.

214. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, wherein said matrix includes at least one other polymer to modify release.

215. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 214, wherein said other polymer is selected from the group consisting of an alkyl cellulose and a water insoluble ammonium methacrylate copolymer.

216. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 215, wherein said other polymer is ethyl cellulose.

217. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 216, wherein said amount of ethyl cellulose is 10 to 50% by weight of the formulation.

218. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, which comprises the following amounts of ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

219. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, which comprises up to 60%

w/w of said active agent, 15 to 50% w/w of neutral poly(ethyl acrylate, methyl methacrylate) copolymer; 5 to 60% w/w of ethyl cellulose; and 7.5 to 20% of plasticiser.

220. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 219, which further contains 5 to 60% of an insoluble ammonium methacrylate copolymer.

221. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 220, which contains 35 to 50% of an insoluble ammonium methacrylate copolymer which is of low permeability and/or 5 to 30% of an ammonium methacrylate copolymer which is highly permeable.

222. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, which contains a bulking agent.

223. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, which contains an opioid and an opioid antagonist.

224. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 223, which comprises 120 to 300 mg of oxycodone multiparticulates and 125 to 175 mg of oxycodone antagonist multiparticulates.

225. (Previously added) The plurality o controlled release f melt extruded multiparticulates of claim 211, which contains oxycodone and naltrexone.

226. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, which contains oxycodone in an amount selected from the group consisting of 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 120 mg and 160 mg of oxycodone.

227. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, suited for once a day dosing.

228. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 227, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH between 1.6 and 7.2 at 37°C of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80% at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hours, and greater than about 50% at 24 hours.

229. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 228, wherein the peak plasma level of oxycodone obtained in vivo occurs at 2 hours to 17 hours after administration of the dosage form.

230. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 227, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method <<7 11>> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 10 to 30% at 1 hour; from 20 to 35% at 2 hours; from 35 to 75%, at 8 hours; and greater than 50% at 16 hours.

231. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, suited for twice a day dosing.

232. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 231, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Paddle Method of the U.S. Pharmacopoeia XXII (1990) at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C of between 12.5 and 42.5% (by wt) oxycodone released after 1 hour, between 25 and 56% (by wt) oxycodone released after 2 hours, between 45 and 75% (by wt) oxycodone released after 4 hours and between 55 and 85% (by wt) oxycodone released after 6 hours.

233. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 231, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method << 7 11 >> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid

without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 0 to 40% at 1 hour; from 20 to 70%, at 2 hours; from 40 to 80%, at 3 hours; from 60 to 95%, at 4 hours; and greater than 70% at 5 hours.

234. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 233, wherein the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the dosage form.

235. (Previously added) The plurality of controlled release melt extruded multiparticulates of claim 211, which shows at least one of the following characteristics (a) to (e) when tested by a test method comprising admixing a dosage amount of the multiparticulates with 10 ml of the liquid in a glass flask and shaking at 500 to 600 oscillations per minute for 15 minutes using a Stuart Scientific Shaker Model SF1:

236. 15 minutes shaking in water at room temperature: less than 7.5% release of active agent;

a. 5 minutes standing in water at 50°C followed by 15 minutes shaking at the same temperature: less than 15% release of active agent;

b. 5 minutes standing at 75°C followed by 15 minutes shaking at the same temperature: less than 20% release of active agent;

c. 5 minutes standing at 100°C followed by 15 minutes shaking at the same temperature: less than 25% release of active agent;

d. 15 minutes shaking in 40% ethanol at room temperature: preferably less than 25% release of active agent.

237. (Previously added) A controlled release pharmaceutical formulation comprising a rubbery matrix including a neutral poly(ethyl acrylate, methyl methacrylate) copolymer and an active agent.

238. (Previously added) The controlled release pharmaceutical formulation of claim 236, wherein said active agent is selected from the group consisting of an opioid, a stimulant, a barbiturate, an anti-depressant, a dissociative anaesthetic, and any two or more of the foregoing.

239. (Previously added) The controlled release pharmaceutical formulation of claim 237, wherein said active agent is oxycodone, or a pharmaceutically acceptable salt thereof.

240. (Previously added) The controlled release pharmaceutical formulation of claim 236, wherein said matrix includes at least one other polymer to modify release.

241. (Previously added) The controlled release pharmaceutical formulation of claim 239, wherein said other polymer is selected from the group consisting of an alkyl cellulose and a water insoluble ammonium methacrylate copolymer.

242. (Previously added) The controlled release pharmaceutical formulation of claim 240, wherein said other polymer is ethyl cellulose.

243. (Previously added) The controlled release pharmaceutical formulation of claim 241, wherein said amount of ethyl cellulose is 10 to 50% by weight of the formulation.

244. (Previously added) The controlled release pharmaceutical formulation of claim 236, which comprises the following amounts of ingredients, based on the total weight of the specified ingredients:

water-insoluble neutral poly(ethyl acrylate, methyl methacrylate) copolymer	15 to 50
active agent	5 to 55
another polymer to modify release	5 to 75
a plasticiser	0 to 25
a lubricant	0 to 25

245. (Previously added) The controlled release pharmaceutical formulation of claim 236, which comprises up to 60% w/w of said active agent, 15 to 50% w/w of neutral poly(ethyl acrylate, methyl methacrylate) copolymer; 5 to 60% w/w of ethyl cellulose; and 7.5 to 20% of plasticiser.

246. (Previously added) The controlled release pharmaceutical formulation of claim 244, which further contains 5 to 60% of an insoluble ammonium methacrylate copolymer.

247. (Previously added) The controlled release pharmaceutical formulation of claim 245, which contains 35 to 50% of an insoluble ammonium methacrylate copolymer which is of low permeability and/or 5 to 30% of an ammonium methacrylate copolymer which is highly permeable.

248. (Previously added) The controlled release pharmaceutical formulation of claim 236, which contains a bulking agent.

249. (Previously added) The controlled release pharmaceutical formulation of claim 236, which contains an opioid and an opioid antagonist.

250. (Previously added) The controlled release pharmaceutical formulation of claim 248, which comprises 120 to 300 mg of oxycodone and 125 to 175 mg of oxycodone antagonist.

251. (Previously added) The controlled release pharmaceutical formulation of claim 236, which contains oxycodone and naltrexone.

252. (Previously added) The controlled release pharmaceutical formulation of claim 236, which contains oxycodone in an amount selected from the group consisting of 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 120 mg and 160 mg of oxycodone.

253. (Previously added) The controlled release pharmaceutical formulation of claim 236, suited for once a day dosing.

254. (Previously added) The controlled release pharmaceutical formulation of claim 252, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH between 1.6 and 7.2 at 37°C of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80%

at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hours, and greater than about 50% at 24 hours.

255. (Previously added) The controlled release pharmaceutical formulation of claim 253, wherein the peak plasma level of oxycodone obtained in vivo occurs at 2 hours to 17 hours after administration of the dosage form.

256. (Previously added) The controlled release pharmaceutical formulation of claim 252, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method <<7 11>> Apparatus 1 at 100 rpm in 900 ml aqueous-buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength; of from 10 to 30% at 1 hour; from 20 to 35% at 2 hours; from 35 to 75%, at 8 hours; and greater than 50% at 16 hours.

257. (Previously added) The controlled release pharmaceutical formulation of claim 236, suited for twice a day dosing.

258. (Previously added) The controlled release pharmaceutical formulation of claim 256, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured by the USP Paddle Method of the U.S. Pharmacopoeia XXII (1990) at 100 rpm in 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37°C of between 12.5 and 42.5% (by wt) oxycodone released after 1 hour, between 25 and 56% (by wt) oxycodone released after 2 hours,

between 45 and 75% (by wt) oxycodone released after 4 hours and between 55 and 85% (by wt) oxycodone released after 6 hours.

259. (Previously added) The controlled release pharmaceutical formulation of claim 256, wherein the active ingredient is oxycodone, and which has an oxycodone dissolution rate in vitro, when measured using the USP Basket Method << 7 11 >> Apparatus 1 at 100 rpm in 900 ml aqueous buffer at pH 1.2 (simulated gastric fluid without enzyme) at 37°C with detection by HPLC with UV at 206 nm wavelength: of from 0 to 40% at 1 hour; from 20 to 70%, at 2 hours; from 40 to 80%, at 3 hours; from 60 to 95%, at 4 hours; and greater than 70% at 5 hours.

260. (Previously added) The controlled release pharmaceutical formulation of claim 258, wherein the peak plasma level of oxycodone obtained in vivo occurs between 2 and 4.5 hours after administration of the dosage form.

261. (Previously added) The controlled release pharmaceutical formulation of claim 236, which shows at least one of the following characteristics (a) to (e) when tested by a test method comprising admixing a dosage amount of the formulation with 10 ml of the liquid in a glass flask and shaking at 500 to 600 oscillations per minute for 15 minutes using a Stuart Scientific Shaker Model SF1:

262. 15 minutes shaking in water at room temperature: less than 7.5% release of active agent;

a. 5 minutes standing in water at 50°C followed by 15 minutes shaking at the same temperature: less than 15% release of active agent;

b. 5 minutes standing at 75°C followed by 15 minutes shaking at the same temperature: less than 20% release of active agent;

c. 5 minutes standing at 100°C followed by 15 minutes shaking at the same temperature: less than 25% release of active agent;

d. 15 minutes shaking in 40% ethanol at room temperature: preferably less than 25% release of active agent.